IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

VALUE DRUG COMPANY	**:**	**CIVIL ACTION**
	:	
v.	**:**	**NO. 21-3500**
	:	
TAKEDA PHARMACEUTICALS, U.S.A., INC., PAR PHARMACEUTICAL, INC., WATSON LABORATORIES, INC. , TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., AMNEAL PHARMACEUTICALS, LLC	**:**	

MEMORANDUM

KEARNEY, J. **November 23, 2022**

A colchicine purchaser claims the brand name manufacturer and three generic colchicine manufacturers violated antitrust law by conspiring to maintain higher prices for brand name and generic colchicine through three separate agreements signed within a few months of each other to settle pending patent litigations shortly before trials. We earlier found the purchaser stated a claim for a single conspiracy among the four manufacturers subject to discovery closing in a month. The parties engaged in vigorous discovery. The purchaser now moves to represent all colchicine purchasers of the brand name and generic colchicine through a class action. The purchaser relies on an expert opinion from a qualified economist to show antitrust impact across all similarly situated colchicine purchasers. The economist assumes facts based on the purchaser's counsel's proffered assumptions in two but-for scenarios which centrally ask us to assume a theory the brand manufacturer would lose the patent litigations and the generics would have earlier moved to market notwithstanding regulatory review. We cannot simply assume facts like an economist to support a theory. We based our decisions on facts in evidence. Our obligation is to rigorously analyze

whether the theory offered by the lead plaintiff seeking class certification is plausible today and at trial based on evidence adduced at and before our evidentiary hearing. The colchicine purchaser before us today did not adduce the evidence allowing us to find its theory of antitrust impact is plausible. We need not address the manufacturers' arguments challenging the alleged number of similarly situated purchasers given this lack of plausibility before us. We deny the purchaser's motion for class certification without prejudice.

I. Background

Physicians prescribe colchicine to treat gout and Familial Mediterranean Fever.[1] Colchicine is sold in both tablet and capsule form and has been used to treat gout since the Sixth Century.[2] Unapproved and unbranded colchicine products have long been on the market.[3]

The United States did not approve or regulate a patented branded colchicine until the last thirteen years. The Food and Drug Administration announced the Unapproved Drugs Initiative in 2006 to bring previously marketed non-Food and Drug Administration approved drugs like colchicine into the approval process to encourage clinical trials of medicines predating federal regulation for safety and effectiveness.[4] Mutual Pharmaceutical Company, a subsidiary of United Research Laboratories, Inc., sought approval of its 0.6mg colchicine tablet in response to the Unapproved Drugs Initiative.[5] The Food and Drug Administration approved its brand name Colcrys as "the first pharmaceutical product contain[ing] colchicine as the sole active ingredient" on July 29, 2009.[6] The Food and Drug Administration granted a seven-year period of marketing exclusivity for colchicine to United Research.[7] United Research launched its brand Colcrys in late 2009.[8]

Takeda Pharmaceuticals U.S.A., Inc. became the first company able to obtain marketing exclusivity for brand Colcrys when it bought United Research in 2012. It holds seventeen patents

for Colcrys which allegedly only covered methods of administering colchicine and not the colchicine itself.[9] Takeda charged 5,733.33% over the 2006 price of colchicine and controlled nearly 100% of sales of single-ingredient colchicine tablets by May 2014.[10] Takeda's seven-year marketing exclusivity ended July 29, 2016 after which competitors could manufacture and market AB-rated generic colchicine.[11]

Par, Hikma, Amneal, Watson, and Mylan file Abbreviated New Drug Applications.

Generic drug companies attempt to bring an AB-rated generic form of a drug once a brand drug comes to market by filing an Abbreviated New Drug Application with the Food and Drug Administration.[12] A brand company like Takeda can lose profits because AB-rated generic versions are usually less expensive and can take significant sales from brand-name counterparts.[13]

Par Pharmaceutical Inc. filed an Abbreviated New Drug Application to market AB-rated generic colchicine in December 2011 and certified Takeda's patents were invalid or not infringed by its AB-rated generic colchicine.[14] The Food and Drug Administration approved Par's filing and granted Par 180 days of statutory exclusivity upon entry of the generic colchicine market because they first filed an Abbreviated New Drug Application.[15] Par obtained tentative Food and Drug Administration approval for its Abbreviated New Drug Application in February 2015.[16]

Hikma International Pharmaceuticals LLC filed a New Drug Application to market colchicine in 0.6-mg capsules for the prophylaxis of gout on October 5, 2012.[17] Hikma received Food and Drug Administration approval and launched colchicine capsules under the brand name Mitigare on October 1, 2014, making it the first entrant of a branded colchicine product since the Food and Drug Administration approval of Colcrys for United Research/Takeda in July 2009.[18]

Amneal Pharmaceuticals LLC filed an Abbreviated New Drug Application in September 2012. Watson Laboratories, Inc., then filed an Abbreviated New Drug Application in February

2013. Both Amneal and Watson certified Takeda's colchicine patents were invalid or not infringed by their AB-rated generic colchicine.[19] Watson and Amneal obtained tentative Food and Drug Administration approval in October 2015 and September 2016 respectively.[20]

Non-party Mylan Pharmaceuticals, Inc filed an Abbreviated New Drug Application for generic colchicine approval in September 2016.[21]

Takeda sues the generic manufacturers for patent infringement.

Takeda sued the generic company filers for patent infringement in the District of Delaware.[22] Takeda first sued Par in August 2013 before suing Amneal and Watson.[23] These suits triggered a thirty-month stay on Food and Drug Administration approval for Par, Amneal, and Watson.[24] Par, Amneal, and Watson could not immediately market their generic colchicine product because of the stay imposed by the patent suits.

Takeda sued Hikma for patent infringement on October 3, 2014 alleging the brand name colchicine capsules Mitigare infringed on five of its Colcrys patents.[25] Hikma launched an approved generic version of Mitigare in January 2015 prompting Takeda to file an amended complaint in its existing patent suit.[26] Judge Andrews granted Hikma's Motion to dismiss the amended complaint in May 2016 and found Hikma's generic colchicine did not infringe on Takeda's patents.[27]

Takeda sued Alkem, Zydus, Dr. Reddy, Mylan, Granules, Hetero, Aurobindo, and Strides for patent infringement after each generic received Food and Drug Administration final approval of their Abbreviated New Drug Application between 2016 and 2018.[28]

Takeda agreed non-party Prasco could market, distribute, and sell authorized generic colchicine during the pendency of the patent suits in January 2015.[29] Takeda received substantial royalties from Prasco's sales.[30] Takeda lost profitability on its brand Colcrys with the addition of a generic colchicine on the market.[31]

Takeda settles with Par, Watson, and Amneal.

Takeda entered into a settlement agreement with Par on November 24, 2015 before their scheduled trial.[32] Takeda and Par agreed Par would have the right to market a generic colchicine subject to a royalty payment to Takeda beginning on July 1, 2018 and Takeda granted Par a license to market its own generic colchicine.[33] Par would step into Prasco's shoes and delay selling its generic colchicine for several years.[34]

Par and Takeda agreed to show their settlement agreement to the other generic litigants Watson and Amneal.[35] Takeda and Watson then settled Takeda's claim for patent infringement against Watson two months (in early 2016) after Takeda settled with Par.[36] Watson obtained the right to launch its generic colchicine no later than October 15, 2020, with an option to enter the market earlier if another generic entered.[37] Takeda then settled with Amneal.[38] Amneal obtained the right to launch its generic colchicine no later than October 15, 2020, unless Takeda licensed another entrant or if another entrant entered the market.[39]

Takeda settles and later again unsuccessfully sues Mylan.

Takeda settled its patent infringement claims against Mylan in November 2017, approximately eighteen months after Judge Andrews granted Hikma's motion to dismiss Takeda's patent infringement counterclaim.[40] Takeda agreed Mylan could enter the Colcrys market "upon a court decision invalidating the patents covering Colcrys."[41] Hikma ultimately prevailed on summary judgment in December 2018.[42] Judge Andrews's decision on Hikma's generic colchicine

involved the same patents challenged in the Par, Amneal, and Watson suits.[43] Takeda did not appeal.[44]

Takeda again sued Mylan for patent infringement in the District of Delaware in December 2019 when it entered the generic colchicine market.[45] Takeda sought a preliminary injunction alleging Mylan breached a contract and infringed its patent.[46] Mylan agreed to stop selling and distributing its generic colchicine while waiting for the Judge Andrews's decision on a preliminary injunction to avoid an emergency motion for temporary restraining order.[47] Judge Andrews denied Takeda's request for a preliminary injunction in January 2020. Mylan reentered the market on March 25, 2020 and the United States Court of Appeals for the Federal Circuit affirmed Judge Andrews' denial of the preliminary injunction on July 31, 2020.[48]

Mylan's market entry allows Par, Amneal, and Watson to enter market.

Mylan's November 2019 entry and 2020 re-entry triggered the "escape clause" in Par, Amneal, and Watson's settlement agreements allowing them to immediately enter the Colcrys market.[49]

Value Drug alleges a single antitrust conspiracy.

Value Drug Company directly purchased Colcrys brand colchicine tablets and AB-rated generic versions of colchicine from Prasco and Par between July 29, 2016 and December 1, 2020.[50] Value Drug, for itself and similarly situated colchicine purchasers, sued Takeda, Watson/Teva, Amneal, and Par on August 5, 2021 for entering a conspiracy "to restrict output and restrain competition" by preventing AB-rated generics of colchicine tablets from coming to market.[51] Value Drug alleges this conspiracy restrained generic competition, caused inflated prices, and allowed Takeda and Par to earn larger profits until other generic competitors launched in 2020.[52]

Value Drug alleges the conspiracy compelled it and the other proposed Class members to pay "artificially inflated prices for their requirements for Colcrys tablets."[53]

Value Drug focuses on a single conspiracy under which Takeda, Par, Amneal, and Watson agreed: Par would not bring its own generic colchicine to market but would instead agree to market Takeda's "authorized generic" previously distributed by Prasco, but Par would not do so until two-and-a-half years after the agreement to lengthen the time Takeda enjoyed the colchicine market competition-free; Par would pay Takeda a "large royalty"; Watson and Amneal would refrain from selling their generic colchicine for several years in exchange for a defined period of time to sell their respective generic colchicine free from all other generic competition; and, Takeda would enter license agreements with other non-conspiring generic companies to delay their entry beyond Watson and Amneal's agreed periods of competition-free sales "thereby giving the co-conspirators long periods of supracompetitive Colcrys profits."[54]

Value Drug initially alleged two claims against Takeda and the three generics—conspiracy to restrain trade in violation of 15 U.S.C. § 1 and conspiracy to monopolize in violation of 15 U.S.C. § 2—and one claim for monopolization against Takeda only in violation of 15 U.S.C. § 2.[55] The brand and generics moved to dismiss for failure to plead antitrust injury. We dismissed Value Drug's claims alleging Takeda, Par, Watson, and Amneal conspired to restrain trade and monopolize the market on the eve of Par's trial with Takeda in November 2015.[56] We found Value Drug did not plead direct or circumstantial evidence supporting the alleged single, horizontal conspiracy but granted leave to amend.[57] Value Drug amended.[58] The brand and generics again moved to dismiss for failure to plead antitrust injury. We denied their Motion to dismiss finding Value Drug cured its evidentiary defects to plead a single horizontal conspiracy but granted the Motion to dismiss as to Value Drug's claim Takeda separately conspired with each Par, Watson,

and Amneal individually to order the market and restrict output (three separate bilateral conspiracies).[59] The single horizontal conspiracy claim among Takeda, Par, Watson, and Amneal is pending before us with a discovery close in a month and trial set for March 2023.

The parties engaged in substantial discovery often leading to discovery disputes. We focused and encouraged discovery based on two phases: (1) fact and expert discovery consistent with the limits set by the Federal Rules of Civil Procedure including merits as warranted necessary to move for class certification and response completed by August 19, 2022 with the parties agreeing to produce all or most of the requested discovery no later than March 3, 2022; and then (2) remaining merits and expert discovery to prepare for summary judgment and trial of either Value Drug's claim or the claims of the defined Class completed by December 22, 2022.[60] We appointed the Honorable Thomas I. Vanaskie (Ret.) as Special Discovery Master on March 15, 2022 with the parties' consent. The parties have had ample opportunity for discovery and filed numerous discovery Motions referred to Judge Vanaskie.[61] We approved and adopted twenty-nine Special Master Recommended Orders from Judge Vanaskie to date. The parties' discovery deadline is December 22, 2022.[62]

II. Analysis

Value Drug now asks to add the other Colcrys purchasers to the case as absent class members. Value Drug moved to certify a class before the close of discovery and before adducing expert testimony on the likelihood of Takeda losing the patent infringement suit. It moves under Federal Rule of Civil Procedure 23(a) and 23(b)(3) seeking to certify a class of approximately fifty purchasers of brand and generic colchicine tablets seeking to recover overcharges for inflated prices for Colcrys tablets because of an antitrust conspiracy "to stave off a 'third wave' of [Abbreviated New Drug Application] filers for as long as possible to prevent incremental price

decrease . . . thereby reducing each sellers' market share and profits" in the Colcrys market.[63] Value Drug claim co-conspirators include Takeda and generic-brands competitors Par, Amneal, and Watson.[64]

Value Drug must satisfy the requirements under Rule 23(a) and either Rule 23(b)(1), (b)(2), or (b)(3).[65] Value Drug seeks class certification under Rule 23(b)(3) requiring common questions of law or fact "predominate" over questions affecting only individual class members, and our finding a "class action is superior to other available methods for fairly and efficiently adjudicating the controversy."[66] We must employ a "rigorous analysis" of the evidence and arguments to determine whether there is actual conformance with Rule 23.[67] We "must resolve all factual or legal disputes relevant to class certification, even if they overlap with the merits—including disputes touching on elements of the cause of action."[68]

We reviewed the parties' thoughtful briefing. Value Drug admittedly bases its arguments almost entirely on the expert opinions of economist Russell L. Lamb, PhD to show the alleged conspiracy resulted in overcharges for brand and generic colchicine for purchasers across the country.[69]

Value Drug attempts to use Dr. Lamb's two "but-for" scenarios to establish antitrust impact and damages for certification.[70] Dr. Lamb claims these two "but-for" scenarios show "what would have occurred in a world free of Defendants' allegedly anticompetitive conduct."[71] Scenario 1 assumes: (a) Par launches on July 29, 2016 after winning its patent cases against Takeda; and (b) Amneal and Watson launch 180 days later on January 25, 2017.[72] Value Drug's counsel instructed Dr. Lamb to assume in the first "but-for" scenario:

> Prasco would have launched an authorized generic ("AG") version of Takeda's branded Colcrys on the same date as it did in the actual world (January 12, 2015), and that Par would have prevailed in the patent litigation brought against it by Takeda and would have launched an AB-rated generic version of Colcrys on July

> 29, 2016 (instead of on July 2, 2018, when it launched in the actual world). I was also instructed to assume under Scenario 1 that Amneal and Teva would have launched their generic Colcrys products on January 25, 2017 (rather than on the dates they launched in the actual world - May 18, 2020 and December 2, 2020, respectively), and that Mylan, Ascend, Zydus, Granules, Dr. Reddy's, and NorthStar would have launched on the same dates they did in the actual world. Thus, under Scenario 1, I assume that there would have been two generics competing in the market from July 29, 2016 through January 24, 2017 (instead of just one, i.e., the AG), four generics competing in the market from January 25, 2017 through November 24, 2019 (instead of just one, the AG), and five or more generics competing in the market thereafter (instead of Mylan launching on November 25, 2019 in competition with the AG and then exiting the market before reentering in March 2020).[73]

Scenario 2 assumes (a) Par forfeits its 180-day regulatory exclusivity; and (b) Amneal and Watson launch May 1, 2017.[74] Value Drug's counsel instructed Dr. Lamb to assume in the second "but-for" scenario:

> Prasco would have launched an AG on the same date as it did in the actual world (January 12, 2015) and that Amneal and Teva would have launched an AB-rated generic version of Colcrys on May 1, 2017 (rather than on May 18, 2020 and December 2, 2020, respectively). I was also instructed to assume under Scenario 2 that Par would have launched generic Colcrys on November 1, 2021, and that Mylan, Ascend, Zydus, Granules, Dr. Reddy's, and NorthStar would have launched on the same dates they did in the actual world. Thus, under Scenario 2, I assume that there would have been a single generic in the market from January 12, 2015 through April 30, 2017 (as there was in the actual world), three generics competing in the market from May 1, 2017 through November 24, 2019 (instead of just the AG), and four or more generics competing in the market thereafter (instead of Mylan launching on November 25, 2019 in competition with the AG and then exiting the market before reentering in March 2020).[75]

Dr. Lamb concludes the conspiracy injured all or nearly all proposed Class members because they paid higher prices than they otherwise would have because of the delayed and ordered entry of multi-source competition for generic colchicine.[76] Dr. Lamb calculated $1.2 billion in aggregate damage under "but-for" Scenario 1 and $772.3 million in aggregate damages under "but-for" Scenario 2.[77] Value Drug's theory of antitrust impact and damages relies on Dr. Lamb's conclusions.[78]

Dr. Lamb conceded he did not analyze "the plausibility of Scenario 1 or Scenario 2 as part of [his] assignment."[79] Dr. Lamb testified his assignment did not include "evaluat[ing] the plausibility of assumptions" or "considering anything about how the assumptions were determined or the parameters that each of Scenario 1 and Scenario 2 contain."[80] Dr. Lamb did not "evaluate the plausibility of those set of facts happening" or "analyze the assumptions with respect to determining whether the pattern assumed with respect to entry by certain generic competitors was . . . plausible."[81] Dr. Lamb testified, specifically for Scenario 2, his assignment did not include "whether there were any facts to support" the assumption Par would have forfeited its 180-day regulatory exclusivity.[82] Dr. Lamb also testified his conclusions could "very well change" if Value Drug's counsel instructed him to make different assumptions for the "but-for" scenarios.[83] Dr. Lamb's "opinions . . . offered in [his] report with respect to impact and aggregate damages are predicated on these two but-for scenarios."[84]

Takeda, Amneal, and Watson counter with expert opinions from Dr. Bruce Strombom.[85] He primarily opines Dr. Lamb premised his analysis on assumed but-for scenarios lacking economic and factual support, Dr. Lamb's reliance on academic literature, forecasts, and averages fails to establish antitrust injury, and Dr. Lamb's methodology for determining class wide overcharges is unreliable.[86]

Counsel asked for oral argument and a hearing. We asked counsel to clarify under Rule 23(b)(3)'s predominance requirement: 1) Dr. Lamb's evidence supporting his assumptions counsel instructed him to make when analyzing his two "but-for" scenarios; 2) whether the individual inquiries, such as market negotiations and customer-driven purchasing decisions, for each proposed Class member needed to establish antitrust impact and injury predominate questions of law and fact common to the proposed Class; and, 3) how Dr. Lamb's model measures damages

consistent with Value Drug's theory of liability and whether those damages are susceptible of measurement across the entire Class.[87]

Dr Lamb testified during our hearing, offering to explain his assessment of the counsel-supplied assumptions underlying his Scenario 1 and Scenario 2. We asked Dr. Lamb if he "assumed what Counsel told [him] was true."[88] Dr. Lamb stated he assumed the truth of the assumptions but had to make sure they were reasonable to apply them to his methodology.[89] Dr. Lamb testified "[i]f they had suggested crazy, unrealistic scenarios, that would have been clear in the record when I went to find the documents that support the damages analysis. And of course, it would have been clear in the other parts of the record. But what I did, as part of the analysis in looking at whether the scenarios could even be thought about, is to look at the facts of the product in question -- of the colchicine product in question."[90] He claims he "wouldn't have taken the assignment, frankly, if they were stupid assumptions."[91] Dr. Lamb also testified before us he analyzed the plausibility of the assumptions even though his assignment did not include the task and he could not have done the assignment without assessing the reasonableness of the "but-for" scenarios.[92] He claims he listed the complete list of reviewed documents in Appendix B of his expert report.[93] Dr. Lamb testified he does not "see how [he] could give an opinion" on how his models would change if Takeda had been successful in its patent suits instead.[94] Dr. Lamb testified he is not an expert in patent law, patent litigation, or Food and Drug Administration regulations or the regulatory process.[95]

We rigorously analyze Value Drug's theory of antitrust impact for both plausibility and evidentiary support. We find Value Drug has not shown a plausible basis convincing us common issues predominate over individual issues and Value Drug has not produced evidence supporting its theory of antitrust impact.

A. Value Drug has not shown a plausible basis to find common issues predominate over the individual issues.

Value Drug must show "(1) a violation of the antitrust laws . . ., (2) individual injury [or impact] resulting from that violation, and (3) measurable damages" and, to certify a class, must show these issues predominate over individual issues by a preponderance of the evidence.[96]

The predominance requirement "tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation."[97] The Supreme Court in Rule 23(b)(3) requires common questions predominate over questions affecting only individual Class members.[98] When "one or more of the central issues in the action are common to the class and can be said to predominate, the action may be considered proper under Rule 23(b)(3) even though other important matters will have to be tried separately, such as damages or some affirmative defenses peculiar to some individual class members."[99] But there are instances when "[q]uestions of individual damage calculations will inevitably overwhelm questions common to the class."[100] "If proof of the essential elements of the cause of action requires individual treatment, then class certification is unsuitable."[101]

Takeda, Amneal, and Watson argue Value Drug's theory of antitrust liability and impact is not plausible.[102] They contend Value Drug has not met its burden of producing evidence through Dr. Lamb showing the plausibility of its theory.[103] Value Drug counters it is "commonplace for class certification and damages experts like Dr. Lamb to rely on plausible factual assumptions."[104] Takeda, Amneal, and Watson challenge Dr. Lamb's first assumption Par would have won its patent infringement lawsuit against Takeda.[105] They argue Dr. Lamb did not analyze the plausibility or offer facts supporting this assumption.[106] Dr. Lamb later testified before us he analyzed the plausibility of the assumptions even though his assignment did not include the task and he could not have done the assignment without assessing the reasonableness of the "but-for" scenarios.[107]

Dr. Lamb relies on the outcome of the "Mitigare Litigation" for his support Par would have won its litigation against Takeda.[108] Takeda, Amneal, and Watson contend economist Dr. Lamb is not an expert who can opine on the plausibility of patent suit outcomes and a patent expert would be necessary to assess the plausibility of the facts underlying the assumption Par would have been successful in its lawsuit against Takeda.[109] Dr. Lamb testified he does not "see how [he] could give an opinion" on how his models would change if Takeda had been successful in its patent suits.[110] We agree with Takeda, Amneal, and Watson.

The predominance requirement of Rule 23(b)(3) requires evidentiary proof.[111] The theory of antitrust impact or injury must be plausible and be "susceptible to proof at trial through available evidence common to the class" at the class certification stage.[112] Plausibility of the theory of antitrust impact is a threshold question for Rule 23(b)(3) predominance purposes.[113] Our Court of Appeals instructed in *In re Hydrogen Peroxide Antitrust Litigation*, "the question at class certification stage is whether, *if such impact is plausible in theory*, it is also susceptible to proof at trial through available evidence common to the class."[114] We must be "satisfied . . . [Value Drug] ha[s] presented a plausible theory for proving a class-wide injury."[115] The law is clear "a class-wide method of proof must be more than 'plausible in theory' and that a district court is to consider 'all relevant evidence and arguments' in predicting whether the class-wide proof will suffice."[116]

Our Court of Appeals first defined what "rigorous analysis" for class certification requires in *In re Hydrogen Peroxide Antitrust Litigation*.[117] We should evaluate the admissibility of expert testimony when determining class certification requirements even if it leads to threshold determinations about the credibility of competing expert opinions.[118] Deciding class certification calls for our "rigorous assessment of the available evidence and the method or methods by which [Value Drug] propose[s] to use the evidence to prove impact at trial."[119] Our "rigorous analysis"

focuses on the evidence underlying Dr. Lamb's models showing Value Drug's theory or antitrust impact and damages.

Our Court of Appeals two years ago clarified "rigorous analysis" mandates the requirements of Rule 23 are met by a preponderance of the evidence, we must resolve all factual or legal disputes relevant to class certification even if they overlap with the merits, and we must consider all relevant evidence and arguments including expert testimony.[120] Our Court of Appeals in *In re Lamictal Direct Purchaser Antitrust Litigation* held it could not determine whether the direct purchaser class satisfied Rule 23's predominance requirement by a preponderance of the evidence without rigorous analysis of the expert reports relying on factual assumptions, and reversed and remanded class certification to the district court for a more fulsome evidentiary analysis.[121] On remand, Judge Vasquez denied class certification, concluding "[p]laintiffs have not shown by a preponderance of the evidence that that they can prove through common evidence that all of Teva's purchasers would have received additional discounts had GSK also launched an authorized generic."[122] The mandates in *In re Lamictal Direct Purchaser Antitrust Litigation* confirm our Court of Appeals requires we conduct a rigorous analysis of fact and expert evidence to determine whether a proposed class satisfied the requirements for class certification.

Value Drug asks us to grant class certification when Dr. Lamb's model showing antitrust impact and damages centrally (and almost entirely) relies on counsel-supplied assumptions. Value Drug cites numerous cases, mostly outside our Circuit or before *In re Lamictal Direct Purchaser Antitrust Litigation*, where judges upheld economist expert's models relying on counsel-supplied assumptions. For example, in *In re Glumetza Antitrust Litigation.*, Judge Aslup rejected the argument the direct purchasers' expert erred by relying on assumptions about when generic entry would have occurred and certified the class.[123] In *In re Loestrin 24 Fe Antitrust Litigation*, Judge

Smith found at class certification the expert's assumptions assuming generic entry date were not sufficiently problematic to render his opinions and testimony unreliable.[124] In *In re Lidoderm Antitrust Litigation*, Judge Orrick granted class certification when the direct purchasers' expert relied on assumptions regarding generic entry dates.[125] Fourteen years ago in *Teva Pharmaceuticals USA, Inc. v. Abbott Laboratories*, Judge Robinson declined to resolve arguments regarding assumptions because the court would need to engage in a merits determination.[126]

We recognize these cases may support Value Drug's position. But these authorities do not govern our analysis. These cases are all outside our Circuit or before the mandates in *In re Lamictal Direct Purchaser Antitrust Litigation*.[127] Our Court of Appeals requires we conduct a rigorous analysis of expert evidence and allows for merit analysis at the class certification stage. "As a review of *Comcast [v. Behrend]* and its progeny reflect, where an expert's model is the basis for a plaintiff's claim of classwide impact and causation, a court is obliged to rigorously examine the soundness of that model at the class certification stage. A court may certify a class under these circumstances only where the Court finds the model methodologically sound."[128]

We are guided by the sound judicial reasoning after *In re Lamictal Direct Purchaser Antitrust Litigation.* Judge Engelmayer rejected an argument a flaw in the expert models would be common to the entire Class and these flaws therefore cannot bear on Rule 23(b)(3) predominance inquiry.[129] Judge Engelmayer further emphasized "circuit courts in antitrust cases have consistently, and correctly, read [the Supreme Court's *Comcast*] decision to require that district courts carefully examine, at the class certification stages, the soundness of an expert's model relied upon to establish classwide impact" and "[d]ecisions from the District of Columbia and Third Circuits usefully illustrate this approach."[130] Judge Engelmayer specifically cited *In Re Lamictal Direct Purchaser Antitrust Litigation* in denying class certification and supporting the assertion

"challenges to an expert's antitrust injury model are properly considered as part of a court's consideration of predominance at the class certification stage."[131] The Court of Appeals for the District of Columbia Circuit similarly affirmed Judge Friedman's denial of class certification when rigorous analysis of the expert's model showed it could not be used as reliable proof of classwide impact.[132] The expert's model before Judge Friedman showed about 12.7% of the proposed class uninjured.[133] We decline to follow Value Drug's reliance on older inapposite authority; we follow our Court of Appeals's approach and rigorously analyze Dr. Lamb's models of antitrust liability and impact today on this fulsome class certification record.[134]

Value Drug centrally (if not entirely) relies on Dr. Lamb to prove their antitrust impact theory.[135] Value Drug's antitrust impact theory alleges generic and brand Colcrys prices would have been lower for all or nearly all proposed Class members but-for the alleged conspiracy.[136] But Dr. Lamb does not cite facts or data supporting this theory of impact or testing its plausibility.[137] Dr. Lamb testifies he did not evaluate "the plausibility of the assumptions," "the plausibility of . . . [the assumptions] happening," or "consider anything about how the assumptions were determined or the parameters that each of Scenario 1 and Scenario 2 contain."[138] Dr. Lamb testified his conclusions about antitrust impact could "very well change" if the underlying assumptions for the "but-for" scenarios change or are disproved.[139] Dr. Lamb argues he analyzed the plausibility of the assumptions even though his assignment did not include the task and he could not have done the assignment without assessing the reasonableness of the scenarios.[140] Takeda, Amneal, and Watson argue Dr. Lamb is not an expert in patent litigation and cannot opine on the plausibility of Par's likelihood of success in its patent suit against Takeda.[141]

We are not satisfied with a qualified economist with no patent experience assessing the plausibility of a patent suit outcome and we are not satisfied with the plausibility of the other

assumptions Dr. Lamb relies upon when he testified multiple times he did not assess their plausibility. Dr. Lamb confirmed he could not provide an opinion on patent suit outcomes on which his models and Value Drug's theory of antitrust impact rely.[142] Value Drug's theory of impact and conspiracy cannot occur as alleged if Takeda won the suit against Par. Evidence providing plausibility of this assumption is critical. We are also not experts in the subjects of these assumptions and cannot assess plausibility without expert testimony. So Value Drug's proof of antitrust impact and calculation of damages relies on assumptions we cannot confirm are plausible. We cannot find Rule 23(b)(3)'s predominance requirement satisfied on this record when Value Drug's class-wide proof of its antitrust impact theory admittedly may not be plausible.

B. Dr. Lamb does not rely on evidence to support Value Drug's theory of antitrust impact.

We must also review the evidence offered to support Value Drug's theory of antitrust impact. Takeda, Amneal, and Watson argue Value Drug's theory of antitrust liability and impact is not supported by evidence.[143] They contend Dr. Lamb's opinions showing class-wide injury is insufficient to satisfy Value Drug's burden because it is predicated only on Counsel's unsupported assumptions.[144] Value Drug's theory of antitrust impact relies on Dr. Lamb.[145] Value Drug counters the Supreme Court's ruling in *Amgen Inc. v. Connecticut Retirement. Plans & Trust Funds* allows its class certification expert Dr. Lamb to rely on assumptions about when generic entry would have occurred absent the alleged conspiracy.[146] They argue the reasoning in *Amgen* and its progeny require "analysis of the merits . . . to the extent that those merits questions implicate whether certain Class Members are injured."[147]

We face evidence adduced by an expert based on assumptions provided to him by counsel with little or no outside verification other than whether the assumption could not possibly be true. Value Drug's counsel instructed Dr. Lamb to assume: 1) Par would have won its patent litigation

against Takeda; 2) Par had the capability of launching on July 29, 2016 instead of July 2, 2018 (actual-world launch); 3) Amneal and Watson/Teva would have launched on the same day in the but-for world; and 4) Watson/Teva would have launched years before their Abbreviated New Drug Application was approved.[148] Value Drug argues "it is commonplace for class certification and damages experts like Dr. Lamb to rely on plausible factual assumptions such as these."[149] We held oral argument to determine what evidence supports these counsel-instructed assumptions which Dr. Lamb relies upon to prove antirust impact.[150]

Dr. Lamb testified he relied on the outcome of *Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical. Corporation* as evidence of the assumption Par would have been successful in its patent suit against Takeda.[151] Value Drug argued evidence supports the other counsel-instructed assumptions relied upon by Dr. Lamb.[152] Dr. Lamb directed us to Appendix B of his report which identifies the documents he reviewed for his expert report.[153] Only one document Value Drug argued supports the assumption "Amneal and Watson would launch 180 days after Par or upon forfeiture" appeared in Dr. Lamb's Appendix B.[154] We cannot confirm whether Dr. Lamb reviewed the rest of the evidence Value Drug argues supports the assumptions.[155] Dr. Lamb also admitted he is not an expert in Food and Drug Administration regulatory processes.[156] Value Drug's theory of antitrust impact relies only on Dr. Lamb's models which is not supported by evidence reviewed by Dr. Lamb. We must deny class certification.

Value Drug primarily relies on the Supreme Court's analysis nine years ago in *Amgen* to assert "a class-wide merits defense does not bar certification."[157] In *Amgen*, the Supreme Court held "Rule 23(b)(3) requires a showing that questions common to the class predominate, not that those questions will be answered, on the merits, in favor of the Class."[158] The Supreme Court held "proof of materiality of alleged misrepresentations is not a prerequisite to class certification in a

securities fraud action based on a fraud on the market theory."[159] Value Drug also relies on *In re K-Dur Antitrust Litigation* to argue its "burden at the class certification stage is not to establish the element of antitrust . . . [but] to demonstrate the element of antitrust impact is capable of proof at trial through evidence that is common to the class."[160] Value Drug cites multiple cases from outside our Circuit where judges rejected the argument class certification should be denied because the expert relied on assumptions about when generic entry would have occurred.[161] They also argue *In re Lamictal Direct Purchasers Antitrust Litigation* is distinguishable because "whether there was a real defense with—Defendants argued was supported by evidence that actually implicated whether some, but not all, of the Class Members were injured."[162] In *In re Lamictal Direct Purchasers Antitrust Litigation*, the pharmaceutical companies "came forward with evidence that they say showed that 25 out of 33 Class Members who only bought the generic were uninjured."[163] Value Drug also contends Dr. Strombom did not opine as to the inaccuracy of Dr. Lamb's assumptions.[164]

Takeda, Amneal, and Watson counter "in this Circuit . . . Class certification decisions need to be made on evidence, not assumption, not on attorney argument, but actual evidence."[165] They argue "[t]he law in this Third Circuit is clear . . . and the standards its announced when District Courts are deciding whether to certify a class . . . ."[166] They argue under *In re Lamictal Direct Purchaser Antitrust Litigation.* and *In re Hydrogen Peroxide Antitrust Litigation*, the question at Class certification is "whether Plaintiffs can demonstrate through common evidence antitrust injury for each class member."[167] Takeda, Amneal, and Watson argue Dr. Lamb's opinion on antitrust impact is predicated on counsel-supplied assumptions and not evidence as required by our Court of Appeals.

The predominance requirement of Rule 23(b)(3) requires evidentiary proof.[168] The theory of antitrust impact or injury must be "susceptible to proof at trial through available evidence common to the class" at the class certification stage.[169] Judge Vasquez when applying our Court of Appeals' mandates on remand in *In re: Lamictal Direct Purchaser Antitrust Litigation* denied class certification when "[p]laintiff's theory is reasonable, but they are missing the critical evidential link emphasized by the Circuit."[170]Judge Vasquez held "[p]laintiffs' theory [of antitrust impact], however rational it may be, is missing critical supporting evidence."[171] We are persuaded our Court of Appeals requires the theory of antitrust impact to be supported by evidence.

Value Drug's reliance on *In re K-Dur Antitrist Litigation* and *Amgen* misses the heart of the issue.[172] Takeda, Amneal, and Watson are not arguing Value Drug needs to establish the element of antitrust impact at the class certification stage like in *In re K-Dur Antitrust Litigation.*[173] They are not arguing those questions common to the class need to be answered on the merits in favor of the class to proceed beyond class certification like *Amgen*.[174] Takeda, Amneal, and Watson are not arguing Value Drug "must first establish it can win" at trial to certify a class today under Rule 23(b)(3).[175] Takeda, Amneal, and Watson are arguing Value Drug's theory of antitrust impact is supported only by counsel-supplied assumptions and not evidence.[176] We engage in an analysis of the evidence underlying the assumptions because those merits questions "implicate whether certain Class Members are injured" under Value Drug's view of *Amgen.*[177] Value Drug's theory of antitrust impact must be supported by evidence at the class certification stage.[178] We find it is not.

Dr. Lamb admitted he did "not . . . analyze the plausibility of any possible facts that are assumed under Scenario 1 or Scenario 2."[179] Value Drug's theory, "however rational it may be, is missing critical supporting evidence."[180] Dr. Lamb did not cite evidence, facts, or data to support

the counsel-instructed assumptions.[181] Dr. Lamb's opinions outlining Value Drug's theory of antitrust impact and injury are supported only by counsel-instructed assumptions and not evidence.[182] We cannot rely on an economic expert's evaluation of how the outcome of one patent case would affect another pending patent case.[183] The evidence Dr. Lamb claims he relies on for this assumption is well beyond his expertise and requires a patent expert. Dr. Lamb acknowledges in his report Value Drug will offer expert testimony in support of the generic entry dates after discovery.[184] Dr. Lamb himself cannot support the generic entry dates on which Value Drug's theory of impact relies. Value Drug argued other evidence supported the counsel-supplied instruction but based on Dr. Lamb's Appendix B we do not conclude he relied on such evidence. The other assumptions also relate to the Food and Drug Administration's regulatory process and pharmaceuticals companies' capabilities which are also beyond the scope of Dr. Lamb's economics expertise.[185] Value Drug's argument Dr. Strombom did not offer an "opinion . . . the assumptions Dr. Lamb utilized were incorrect" is irrelevant because the burden of producing evidence is Value Drug's alone.[186]

Value Drug does not meaningfully distinguish our Court of Appeals' mandates in *In Re Lamictal Direct Purchaser Antitrust Litigation*. Dr. Lamb specifically testified if his unsupported assumptions for the "but-for" models were to change, his conclusions regarding antitrust impact might be different.[187] Dr. Strombom's example of changing the generic entry date for Amneal and Watson in Scenario 2 results in twenty-five percent of the proposed Class being uninjured.[188] Takeda, Amneal, and Watson produced evidence there could be many uninjured Class member through Dr. Strombom if Dr. Lamb changed his unsupported assumptions.[189] This evidence "implicates whether some, but not all, of the Class Members were injured."[190] Judge Vasquez denied class certification on remand in *In re Lamictal Direct Purchaser Antitrust Litigation* for

generic-purchasers when the theory of antitrust impact relied on "an assumption, not evidence, and Plaintiffs have the burden of producing such evidence and proving the issue by a preponderance of the evidence."[191] We must do the same.

This sizable portion of the Class possibly being uninjured depending on the reliability and accuracy of Dr. Lamb's model is similar to the unreliable model dismissed in *In re Rail Freight Fuel Surcharge Antitrust Litigation.*[192] An unreliable model showing uninjured class members cannot be used as the basis for predominance.[193] Value Drug has not demonstrated they can prove antitrust impact through common evidence when their model illustrating the theory of antitrust impact is not based on evidence.[194] Value Drug failed to meet their burden of coming forward with evidence to support the assumptions on which Dr. Lamb's opinions are based.

C. We do not opine on the Rule 23(a) requirements or other aspects of Rule 23(b)(3).

Our decision to deny class certification without prejudice does not consider the four requirements of numerosity, commonality, typicality, and adequacy of representation under Rule 23(a), the superiority prong of Rule 23(b)(3), or other arguments relating to predominance under Rule 23(b)(3). Today's denial of the pending Motion for class certification focuses solely on the plausibility of Value Drug's theory of antitrust impact and the missing evidential link required by our Court of Appeals. We leave those issues for another day should Value Drug returns with evidence allowing us to find it meets the rigorous analysis of its theories before certifying the class.

III. Conclusion

We agree with Takeda, Amneal, and Watson a threshold showing of plausibility has not been met. We deny Value Drug's Motion for class certification without prejudice.

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[1] Gout is a type of severe arthritis occurring from high levels of uric acid in the blood. Familial Mediterranean Fever is an auto-inflammatory disease resulting in fever, pain, and swelling of the

joints. App. 0016a ¶¶ 26–27. We require the parties submit an Appendix supporting a motion for class certification under our governing Policies. Value Drug submitted an Appendix at ECF Doc. No. 483-2, Bates stamped 0001a–1107a, Takeda, Amneal, and Watson submitted a Response Appendix at ECF Doc. No. 527-1, Bates stamped 1108a–1273a, and Value Drug submitted a Reply Appendix at ECF Doc. No. 543-1, Bates stamped 1274a–1481a.

[2] App. 0016a ¶ 27.

[3] App. 0364a ¶ 61.

[4] App. 0017a ¶ 28.

[5] App. 0016a–0017a ¶¶ 26–29.

[6] ECF Doc. No. 1 ¶ 29, 32.

[7] App. 0402a.

[8] App. 0017a ¶ 29. The Food and Drug Administration granted a three-year exclusivity period for treatment of acute gout flares and a seven-year exclusivity period for treatment of Familial Mediterranean Fever. App. 0018a ¶ 30.

[9] App. 0018a ¶ 30.

[10] App. 0018a ¶ 30–31.

[11] App. 0402a. "An AB rating means that the generic drug is pharmaceutically equivalent and bioequivalent to the corresponding reference-listed brand drug." ECF Doc. No. 1 ¶ 37. "An AB-rating is particularly significant because . . . pharmacists may (an in many states, must) substitute an AB-rated generic version of a drug for the brand-name drug automatically at the pharmacy counter, without seeking or obtaining permission from the prescribing physician." *Id.*

[12] ECF Doc. No. 1 ¶ 33–36. *See also* App. 0591a–0592a.

[13] App. 0032a–0038a; 0596a–0598a.

[14] App. 0119a. ¶ 29.

[15] App. 0199a ¶24.

[16] App. 0200a ¶ 25.

[17] App. 202a ¶ 28.

[18] *Id.*

[19] App. 0201a–0202a.

[20] App. 0201a–0202a ¶ 27.

[21] App. 0202a–0203a.

[22] App. 0199a–0203a ¶ 24–28.

[23] *Id. See also Takeda Pharm. U.S.A., Inc. v. Par Pharm., Inc.*, No. 13-1524 (D. Del. Aug. 30, 2013); *AR Holding Co., Inc. v. Par Pharm., Inc.*, No. 12-419 (D. Del. Apr. 4, 2012); *Takeda Pharm. U.S.A., Inc. v. Amneal Pharm.*, LLC, No. 13-1729 (D. Del. Oct. 21, 2013); *Takeda Pharm. U.S.A., Inc. v. Watson Lab'ys, Inc.*, LLC, No. 14-268 (D. Del. Feb. 27, 2014).

[24] App. 0201a ¶ 26.

[25] App. 0202a ¶ 28.

[26] App 0203a. ¶ 29.

[27] *Takeda Pharms. USA, Inc. v. W.-Ward Pharm. Corp.*, 72 F. Supp. 3d 539 (D. Del. 2014), *aff'd* (Fed. Cir. 15-1139, 15-1142 Jan. 9, 2015), *aff'd in part, appeal dismissed in part sub nom. Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625 (Fed. Cir. 2015); App. 0203a ¶ 29.

[28] App. 0023a ¶ 39.

[29] *See* App. 0645a, 1064a.

[30] *Id.*

[31] *See* App. 0641–0643a.

[32] App. 0200a ¶ 25.

[33] *Id.*

[34] ECF Doc. No 483-1 at 3. *See* App. 0649a–0660a.

[35] App. 665a–667a.

[36] App. 0201a ¶ 26.

[37] App. 0726a–0736a.

[38] App. 0696a-0707a.

[39] *Id.*

[40] App. 0204a. ¶ 30.

[41] ECF Doc. No. 1 ¶ 64.

[42] App. 0021a ¶ 35.

[43] *Id.*

[44] ECF Doc. No. 1 ¶ 65.

[45] App. 0024 ¶ 41.

[46] *Id.*

[47] *Id.*

[48] *Id.*

[49] ECF Doc. No. 1 ¶ 57. ("Par, Watson, and Amneal would refrain from launching their own generic versions of Colcrys for so long as non-conspirators did so. That is, the co-conspirators agreed that if a non-conspiring seller of generic Colcrys entered the market, Par, Watson, and Amneal could do so.").

[50] App. 0114a.

[51] ECF Doc. No 1 ¶¶ 3, 60.

[52] ECF Doc. No. 483-1 at 5.

[53] ECF Doc. No. 1 at ¶ 72.

[54] *Id.* at ¶ 3(a)–(e). The alleged conspiracy is somewhat generally similar to the conspiracy studied by the courts in *FTC v. Avtavis*, 570 U.S. 136 (2013) ("pay-for-delay" patent litigation settlement agreements where brand drug companies pay generic-drug companies in return for a delay in marketing the generic product).

[55] ECF Doc. No. 1.

[56] *Id.* ¶ 54; ECF Doc. No. 153.

[57] ECF Doc. No. 157.

[58] ECF Doc. No 163.

[59] ECF Doc. No. 207.

[60] ECF Doc. No 94 at 1–2.

[61] There have been over 450 docket entries since the appointment of Judge Vanaskie, many of which are discovery disputes. Judge Vanaskie currently has a Rule 45(d)(1) Motion for sanctions and a Rule 37(c)(1)(C) Motion for sanctions for abusing the discovery process pending before him. ECF Doc. No. 514; ECF Doc. No. 585. Judge Vanaskie also has Motion to compel pending before him. ECF Doc. No. 634.

[62] ECF Doc. No. 94. At oral argument, Value Drug's counsel stated fact discovery is still ongoing. ECF Doc. No. 620 at 8:7–11. We asked counsel whether it makes sense to defer this Motion for certification until the close of discovery because there could be some evidence to back the assumptions which are not included in the expert reports. ECF Doc. No. 620 at 152:5–25. Takeda stated additional discovery is not needed because Value Drug has "sophisticated Counsel. They've been on notice. They knew what they needed to do [for class certification]. They chose not to do it. Giving them a do-over and having us incur the time and expense to relitigate this issue again." *Id.* at 180:22–181:7. Value Drug's counsel also stated "we think the record is more than sufficient" for class certification purposes. *Id.* at 221:9–222:4.

[63] ECF Doc. No. 207 at 8 n.25. Value Drug moves we define its proposed class as: "All persons or entities in the United States and its territories and possessions, including the Commonwealth of Puerto Rico, who directly purchased branded or generic Colcrys tablets from Takeda, Prasco, or Par at any time from July 29, 2016 until December 1, 2020 (the "Class"). Excluded from the Class are Defendants, their officers, directors, management, employees, subsidiaries, and affiliates, and all federal governmental entities." ECF Doc. No. 483 at 2.

[64] We approved Value Drug and Par Pharmaceuticals, Inc. joint stipulation and dismissed Par Pharmaceuticals, Inc. with prejudice following its bankruptcy filing. ECF Doc. Nos. 518, 521.

[65] *Sullivan v. DB Invs., Inc.*, 667 F.3d 273, 296 (3d Cir. 2011) (en banc).

[66] Fed. R. Civ. P. 23(b)(3).

[67] *Marcus v. BMW of N. Am.*, LLC, 687 F.3d 583, 591 (3d Cir. 2012) (citing *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 322 (3d Cir. 2008)).

[68] *Marcus*, 687 F.3d at 591.

[69] App. 0010a ¶ 14.

[70] App. 0010a ¶ 14. *See also* ECF Doc. No 483-1 at 14–15.

[71] App. 0006a ¶ 7; ECF Doc. No. 483-1 at 14.

[72] App. 0006a ¶ 8.

[73] App. 0007a ¶ 8.

[74] App. 0007a ¶ 9.

[75] App. 0007a ¶ 9. A summary table of generic Colcrys entry dates in the two but-for scenarios and the actual world is found at App. 0008a, Tbl. 1.

[76] App. 0010a ¶ 14.

[77] *Id.*

[78] ECF Doc. No. 483-1 at 14–15; App. 0010a ¶ 14.

[79] App. 0145a.

[80] App. 0144a.

[81] App. 0145a.

[82] App 1112a.

[83] App. 0147a. *See also* App. 1113a ("If you ask me to make different assumptions, I could do the analysis, and the analysis might be different, as it was for these two class members under scenario 2 compared to scenario 1."). For example, Takeda's expert Dr. Bruce Strombom explained moving generic entry to February 17, 2019 instead of May 1, 2017 would result in 25% of the Class being uninjured. App. 0217a ¶ 50.

[84] App. 0141a.

[85] App. 0185a.

[86] App. 0211a, 0218a, 0222a, 0266a.

[87] ECF Doc. No. 545 at 1–2 n. 1.

[88] ECF Doc. No. 620 at 37:20–25.

[89] *Id.* at 38:1–3.

[90] *Id.* at 38:12–20.

[91] *Id.* at 49:5–8.

[92] *Id.* at 91:21–92:24.

[93] App. 0098a–0101a; ECF Doc. No. 620 at 91:4–10.

[94] ECF Doc. No. 620 94:19–95:6.

[95] *Id.* at 90:19–91:3.

[96] *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d at 311, 321.

[97] *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623 (1997).

[98] *In re Niaspan Antitrust Litigation*, 397 F.Supp.3d 668, 682 (E.D. Pa Aug. 14, 2019) (citing *Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 568 U.S. 455, 469 (2013)).

[99] *Tyson Foods, Inc.*, 577 U.S. at 453 (quoting 7AA C. Wright, A. Miller, & M. Kane, Federal Practice and Procedure § 1778, pp. 123–124 (3d ed. 2005)).

[100] *Comcast Corp. v. Behrend*, 569 U.S. 27, 34 (2013).

[101] *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d at 311 (citing *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 172 (3d Cir.2001)).

[102] ECF Doc. No. 527 at 19.

[103] *Id.* at 20.

[104] ECF Doc. No. 543 at 9.

[105] ECF Doc. No. 620 at 40:1.

[106] *Id.* at 40:1-3.

[107] *Id.* at 91:21–92:24.

[108] App. 0021 ¶ 35.

[109] ECF Doc. No. 620 at 40:4–18.

[110] *Id.* at 94:19–95:6.

[111] *Comcast*, 569 U.S. 33.

[112] *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d at 325.

[113] *Harnish v. Widener Univ. Sch. of L.*, 833 F.3d 298, 304 (3d Cir. 2016) ("The court cannot rely on a mere "threshold showing" that a proposed class-wide method of proof is "plausible in theory.").

[114] *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d at 325 (emphasis added).

[115] *Reyes v. Netdeposit, LLC*, 802 F.3d 469, 489 (3d Cir. 2015).

[116] *Harnish*, 833 F.3d at 306 (quoting *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d at 325).

[117] *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305 at 307.

[118] *Id.*

[119] *Id.*

[120] *In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184, 191 (3d Cir. 2020).

[121] *Id.*

[122] *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-995, 2021 WL 2349828, at *21 (D.N.J. June 7, 2021).

[123] *In re Glumetza Antitrust Litig.*, 336 F.R.D. 468 (N.D. Cal. 2020).

[124] *In re Loestrin 24 Fe Antitrust Litig.*, No. 13--2472, 2019 WL 3214257, at *4 (D.R.I. July 2, 2019).

[125] *In re Lidoderm Antitrust Litig.*, No. 14-02521, 2017 WL 679367, at *1 (N.D. Cal. Feb. 21, 2017).

[126] *Teva Pharms. USA, Inc. v. Abbott Lab'ys*, 252 F.R.D. 213, 228 (D. Del. 2008).

[127] *In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184 at 195.

[128] *In re Aluminum Warehousing Antitrust Litig.*, 336 F.R.D. 5, 46 (S.D.N.Y. 2020).

[129] *Id.*

[130] *Id.* at 47.

[131] *Id.*

[132] *In re Rail Freight Fuel Surcharge Antitrust Litig.*, No. 1869, 934 F.3d 619, 623 (D.C. Cir. 2019).

[133] *Id.*

[134] Value Drug moved two days ago to add evidence adduced in the last week and amend its class definition with the new evidence. ECF Doc. No. 647. We today deny this attempt to re-open the record closed earlier this month after lengthy study. The request is curious because we offered Value Drug's counsel the opportunity to withdraw the pending motion for certification and seek

relief after adducing more evidence. Value Drug's counsel declined our offer a little over three weeks ago during our oral argument and evidentiary hearing and asked to move forward on the voluminous record then before us. We accepted Value Drug's decision and will not allow do-overs of a pending motion given the parties' and our efforts in reliance on Value Drug's decision.

[135] ECF Doc. No. 483-1 at 14–15.

[136] *Id.* at 7.

[137] ECF Doc. No. 527 at 16.

[138] App. 1044a–45a.

[139] App. 0147a, 1113a.

[140] ECF Doc. No. 620 at 91:21–92:24.

[141] *Id.* at 39–40.

[142] *Id.* at 94:19–95:11.

[143] ECF Doc. No. 527 at 19.

[144] *Id.*

[145] ECF Doc. No. 483-1 at 14–15.

[146] ECF Doc. No. 543 at 9–10.

[147] ECF Doc. No. 620 at 14:14–23.

[148] App. 0006a ¶ 8.

[149] ECF Doc. No. 5.

[150] ECF Doc. No. 545 at n.1

[151] *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharmaceutical. Corp.*, 785 F.3d 625 (Fed. Cir. 2015). *See* ECF Doc. No. 620 at 33:17–36:7. *See also* App. 0021a ¶35.

[152] ECF Doc. No. 620 at 33:17–59:18.

[153] App. 0098a–0100a. *See also* ECF Doc. No. 620 at 56:17–57:7.

[154] AMNL_COL_00014697. *See* App. 0098a-0100a.

[155] PAR-COL_000289363, PAR-COL_000000032, PAR-COL-000210677, TAK-COLCRYS-01704162, TEVA_COL_00164515, TEVA_COL_00021668, and TAK-COLCRYS-01704162. *Compare* 0098a–0100a.

[156] ECF Doc. No. 620 at 90:24–91:3.

[157] ECF Doc. No. 543 at 9.

[158] *Amgen Inc. v. Connecticut Ret. Plans & Tr. Funds*, 568 U.S. 455, 459 (2013).

[159] *Id.* at 459–60.

[160] *In Re K-Dur*, 686 F.3d 197, 222 (3d Cir. 2012). *See* ECF Doc. No. 543 9–10.

[161] ECF Doc. No. 9–11; *see In re Glumetza Antitrust Litig.*, 336 F.R.D. at 477; *In re Loestrin 24 Fe Antitrust Litig.*, 2019 WL 3214257 at 13; *In re Lidoderm Antitrust Litig.*, 2017 WL 679367, at 12–13.

[162] ECF Doc. No. 620 at 16:1–8.

[163] *Id.*

[164] ECF Doc. No. 543 at 9.

[165] ECF Doc. No. 620 at 155.

[166] *Id.*

[167] *In re: Lamictal Direct Purchaser Antitrust Litig.*, 2021 WL 2349828 at 17; *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d at 325.

[168] *Comcast*, 569 U.S. 33.

[169] *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d at 325.

[170] *In re Lamictal Direct Purchaser Antitrust Litig.*, 2021 WL 2349828 at 21 (denying Class certification when Dr. Lamb did not show evidence all purchasers would have received a discount and holding class wide antitrust injury did not exist).

[171] *Id.*

[172] We distinguish Value Drug's reliance on cases outside this Circuit because of the emphasis on evidentiary support at the class certification stage required by our Court of Appeals. *In re Lamictal Direct Purchaser Antitrust Litig.*, 2021 WL 2349828 at 21 ("Plaintiffs theory is reasonable, but they are missing the critical evidential link emphasized by the Circuit.").

[173] *In Re K-Dur*, 686 F.3d at 222. *See* ECF Doc. No. 543 9–10.

[174] *Amgen*, 568 U.S. at 459–60.

[175] *Id.* at 460.

[176] ECF Doc. No. 527 at 15–16.

[177] Amgen, 568 U.S. at 460; ECF Doc. No. 620 at 14:14–23.

[178] *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d at 325.

[179] App. 0145a.

[180] *Id.*

[181] App. 0006a–0007a ¶¶ 7–9. *See also* ECF Doc. No. 527 at 16.

[182] *See* App. 0145. ("I'm not analyzing the plausibility of Scenario 1 or Scenario 2 as part of my assignment. That's beyond the scope of my assignment.").

[183] ECF Doc. No. 620 at 25:19–4.

[184] App. 0008a at n.15. *See also* ECF Doc. No. 620 at 42:5–25. (Value Drug arguing they will have patent expert evidence supporting generic entry date after close of discovery in January 2023).

[185] ECF Doc. No. 620 at 90:24–91:3.

[186] ECF Doc. No. 543 at 9. *See also In re Lamictal Direct Purchaser Antitrust Litig.*, 2021 WL 2349828 at 20.

[187] App. 0147, 1113a.

[188] App. 0217a ¶ 50.

[189] *Id.*

[190] ECF Doc. No. 16:1–5.

[191] *In re Lamictal Direct Purchaser Antitrust Litig.*, 2021 WL 2349828 at 20.

[192] *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 934 F.3d at 623.

[193] *Id.*

[194] *See In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d at 325.